REGISTRATION REQUIREMENTS FOR A GOVERNMENT AGENCY IMPORTING A PHARMACEUTICAL PRODUCT WITH A REGISTERED COUNTERPART BRAND IN THE PHILIPPINES

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I
Rationale

The Philippines has one of the highest drug prices in the ASEAN region (J. Lim Study, 1997, DOH-DTI-Comparative Drug Price Survey in ASEAN countries, 1999). For this reason, President Joseph Ejercito Estrada has signed a memorandum last 26 April 2000 directing the Departments of Health and the Trade and Industry to intensify their efforts in making essential and life-saving medicines affordable and accessible to the public, especially to the poorer segments of the society.

A key strategy to lower drug prices is the importation of finished drug products from other countries where these are cheaper than in the Philippines. One component of this strategy is the parallel importation scheme where a similarly branded product that is cheaper in other countries will be imported and introduced in the local market. These imported products will be registered in the Bureau of Food and Drugs (BFAD) before these are sold to the public.

In view of this, the following registration requirements for a government agency importing a pharmaceutical product with a registered counterpart brand in the Philippines are hereby prescribed:

II
General Requirements:

1. Application Letter

The application/covering letter shall provide the following information:

a. Generic name and Brand name of the product

b. Dosage strength and dosage form

c. Complete names and addresses of the manufacturer of the product and distributor-importer

2. A copy of a valid License to Operate and Drug Distributor-Importer reflecting the source or country of origin of the product and the list of products to be imported.

Only distributor-importers that are government agencies and are authorized by BFAD shall be allowed to import and register pharmaceutical products with a registered counterpart brand in the Philippines.

3. Proof that the exporter has a business relationship with the manufacturer or authorized distributor. Such proof may consist of official receipts, sales invoices, distributorship agreements, or other similar documents.

4. Official receipts and/or sales invoices establishing that the delivered pharmaceutical products were sourced from a distributor licensed by the manufacturer in the country of origin to sell its products. These official receipts and/or sales invoices shall identify the batch/lot number and the expiry dates.

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5. Specimens of the proposed label and other labeling materials such as inserts, brochures, etc. to be used for the imported product shall be exempted from the generic labeling requirements. If not already present on the immediate label and box, the following shall be printed or shall appear on a stick-on label: the phrase, “Imported by (name of government agency)”, the suggested retail price of the product, and other labeling requirements.

6. Samples submitted to BFAD shall be in market or commercial presentation and shall be sufficient for use in assessing the product’s conformity with the given test specifications plus sufficient retention sample for future reference.

7. Full laboratory testing by BFAD of every batch/lot number of product per importation.

III
Effectivity:

This Order shall take effect fifteen (15) days from the date of its publication in two (2) newspapers of general circulation.

Adopted: 14 July 2000

(SGD.) ALBERTO G. ROMUALDEZ, JR. M.D.
Secretary of Health

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